Practitioner's Docket No.: 789_070 CON2 ***PATENT***

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Toshikazu HIROTA and Takao OHNISHI

Ser. No.: 10/757,264 Group Art Unit: 1634

Filed: January 14, 2004 Examiner: Betty J. Forman

Confirmation No.: 4900

For: BIOCHIP

RULE 132 DECLARATION

I, Tadahiko Inukai, a citizen of Japan, hereby declare and state that:

1. I received a BS Degree in Agricultural Chemistry from Nagoya University in 1966.

2. I had been employed by Amano Pharmaceutical Co. Ltd. since April of 1966. During my employment at Amano Pharmaceutical Co. Ltd. I had been involved in R&D section and Planning section. In 1989, I resigned from Amano Pharmaceutical Co. Ltd. and founded Biseien Co. Ltd. consulting in field of Biotechnology. I also work as the coordinator of Osaka Prefectural University since 2003, and work as the adviser of Nonprofit Organization Bio Factory Central Japan since 2004.

3. I am familiar with the prosecution history of the above-identified application, and have reviewed the Office Action mailed July 17, 2007. I understand that the PTO Examiner is taking the position that the present specification does not enable any other capture materials other than DNA. I also understand that applicants have now limited the claims to capture materials that are dissolved in an aqueous solution. I will explain below why I believe that the present specification is enabling for all types of capture materials dissolved in aqueous solutions.

4. The ink-jet spotting device described in the specification of the present application is similar to traditional, well-known droplet devices in terms of the required characteristics of the solution that will be emitted from the device . The present specification discloses, starting on page 11, line 13, that the ink -jet spotting device of the present invention forms a spot by discharging a capture solution into atmospheric air and allowing a droplet of the capture solution to arrive at a base plate. Accordingly, the performance and reliability of the ink -jet device used in the present invention will be operationally affected by the same fluid characteristics of a capture solution to be dispensed by more traditional means. Specifically, the droplet size is determined directly by the capture solution's surface tension, and the reliability of the drop let formation is determined by the capture solution's viscosity.

5. The surface tension and viscosity of a capture solution are primarily influenced by the buffer solution used as the carrier for the capture material. I would understand the rudimentary alterations (i.e., varying concentration of buffers and materials) required to create solutions suitable for deposition by an ink-jet device without any undue experimentation. In any event, I would not expect the ink-jet device of the present invention to be overly sensitive to these fluid characteristics, because the specification discloses, on page 11, lines 16 -21, that the amount of a solution sample deposited can be controlled electronically simply by varying the force of the discharge and the number of discharges of fluid per unit time. Therefore, very little experimentation would be required on my part to determine optimal solution characteristics when practicing the present invention using a variety of different capture materials, provided they are dissolved in an aqueous solution .

6. The optimal solution characteristics for capture solutions to be deposited by the ink-jet spotting device of the present invention are obtained by following the basic guidelines disclosed in the specification. The optimal solution characteristics involve dissolving an organic capture material (e.g., powdered DNA, powdered antigen, powdered reagent, powdered cells, enzymes, etc.) into an aqueous solution. The present specification provides, on page 16, lines 12 -20, that a sample solution is prepared by completely dissolving powered organic capture material into a x1 TE buffer. In the same section, the specification defines that the concentration of the organic material is provided in a concentration of 0.1 to 10 μg/μ liter. Further, the specification provides, in the paragraph bridging pages 16 and 17, that the buffer solution is an aqueous solution containing water and NaCl, or an aqueous solution containing polymer.

7. While the present specification provides only a single specific example of an actual capture material (DNA), it clearly enables me to use the present invention in connection with other capture materials, provided they are dissolved in an aqueous solution. The fluid characteristics (i.e., surface tension and viscosity) that are important for ensuring proper ink-jet operation are predominantly dictated by the aqueous nature of the solution in which the capture material is dissolved, not the capture material itself.

8. In summary, I believe that a wide variety of capture solutions could be reliably deposited on a base substrate, without undue experimentation, so long as one follows the basic guidelines provided in the specification. The most significant factor for ensuring proper functioning of the ink-jet device disclosed in the present specification is that the capture solution is aqueous, as applicants have now clarified in the pending claims.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statement s and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NOV. 12, 2007 Tadahiko Inukai

Date